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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,912	03/08/2004	James M. Brugger	53951-123	1670

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PROSKAUER ROSE LLP  
PATENT DEPARTMENT  
1585 BROADWAY  
NEW YORK, NY 10036-8299

EXAMINER
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HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/796,912	<b>Applicant(s)</b> BRUGGER ET AL.	
	<b>Examiner</b> Melanie J. Hand	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/30/04, 11/10/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

The election of species requirement has been withdrawn.

### ***Priority***

Acknowledgment is made of applicant's claim for priority as a continuation-in-part of copending Application No. 09/894,236, filed on June 27, 2001, now U.S. Patent No. 6,955,655, which is a continuation-in-part of copending Application No. 09/865,905, filed on May 24, 2001, now U.S. Patent No. 6,852,090, which is a continuation of copending Application No. 09/513,773, filed on February 25, 2000, now U.S. Patent No. 6,579,253.

### ***Information Disclosure Statements***

The information disclosure statements (IDS) submitted on July 30, 2004 and November 10, 2006 was filed after the mailing date of the Application on March 8, 2004. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, 8, 10 and 14 of copending Application No. 10/796,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application is an obvious broader variant of claims 2, 4, 8 and 10 of the copending application and claim 9 of the instant application is a broader variant of claim 14 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/163,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the copending application is an obvious broader variant of claim 1 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Objections***

Claim 4 is objected to because of the following informalities: the phrase "at least one actuator" lacks proper antecedent basis in claim 1 from which it depends. Appropriate correction is required.

Claim 13 is objected to because of the following informalities: the phrase "said fluids" lacks proper antecedent basis. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Dennehey (U.S. Patent No. 5,462,416).

With respect to **claim 1**: Dennehey teaches a renal replacement therapy system, comprising: a blood treatment device 10 with at least one peristaltic pump mechanism 254 (Col. 20, lines 56-59); a fluid circuit 18 with respective portions 22A/B/C to engage said at least one peristaltic pump mechanism 254 (Col. 15, lines 37-43, Col. 20, lines 56-60, Col. 23, lines 3-7); said fluid circuit 18 including separate engagement elements 26,256 that may be brought together around said respective portions 22A/B/C to engage said at least one peristaltic pump mechanism fluid circuit portions 22A/B/C by forcing a first of said engagement elements 26 including panels 118 against a second of said engagement elements 256 (Col. 6, lines 52-57, Col. 21, lines 22-25);

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said fluid circuit 18 and said blood treatment device 10 being arranged such that multiple separate fluid flows  $F_N$  may be maintained by an operation of said at least one peristaltic pump 254 merely by means of said forcing, whereby an installation and set up of said fluid circuit 18 is simplified. (Col. 21, lines 22-25)

With respect to **claim 2**: The fluid circuit 18 includes an extracorporeal blood circuit. (Col. 18, lines 50-54, Col. 19, lines 5-8)

With respect to **claim 3**: The fluid circuit 18 is configured for circulating blood from an individual through the blood treatment device to remove waste and to return blood and replacement fluid to the individual after removal of waste and said respective portions include a first portion 46 for conveying waste (Col. 19, lines 20-22), a second portion 32 for conveying blood (Col. 18, line 67 – Col. 19, line 1), and a third portion 48 for conveying replacement fluid. (Col. 19, lines 5-8)

With respect to **claim 4**: At least one actuator 236 includes a peristaltic pump 254 with a single rotating element 292 that pumps blood through multiple ones of said respective portions 22 A/B/C, said respective portions 22 A/B/C carrying different fluids including at least blood and another fluid in the form of an anticoagulant. (Col. 16, lines 30-33)

With respect to **claim 6**: The at least another fluid includes waste fluid in the form of platelet-poor-plasma (PPP) used as “final flush fluid”. (Col. 18, lines 15-17)

With respect to **claim 7**: The first of said engagement elements 26 includes tubing 80 which in turn includes a filter 82. (Col. 19, lines 23-26)

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With respect to **claim 8**: The first of said engagement elements 26 is permanently attached to said fluid circuit forming a sterile consumable component 14 which is replaced after a fixed number of treatments. (Col. 5, lines 45-47)

With respect to **claim 9**: Dennehey teaches a method of performing renal replacement therapy using a blood treatment device 10 with at least one peristaltic pump mechanism 254 having separate engagement elements 26,256, a fluid circuit 18 with respective portions 22A/B/C to engage said at least one peristaltic pump mechanism 254, comprising the steps of: locating said fluid circuit respective portions between said separate engagement portions (Col. 21, lines 20-22); attaching said engagement portions together to squeeze said respective portions therebetween (Col. 21, lines 22-25); operating a pump 292 in one of said engagement portions 256 to convey at least blood and at least one other fluid in order to perform a therapeutic treatment. (Col. 16, lines 30-33, Col. 20, lines 56-67)

With respect to **claim 10**: The respective portions 22A/B/C include fluid lines  $F_N$  and said step of locating includes laying said fluid lines on a peristaltic pump 254. (Col. 20, lines 56-59)

With respect to **claim 11**: Dennehey further teaches disposing of said first of said engagement elements 26 and replacing it with another after a fixed number of treatments.(Col. 5, lines 45-47)

With respect to **claim 12**: The processing assembly 14 including tray 26 is a single use item, thus the fixed number is one. (Col. 5, lines 45-47)

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With respect to **claim 13**: Dennehey teaches a renal replacement therapy system, comprising: a blood treatment machine 10 having at least one pump 292 and at least one pump race 296 configured to engage tubes 134,136 of a fluid circuit 18 (Col. 23, lines 10-13); a replaceable tubing set with tubes 134,136 configured to engage with said at least one pump 292 (Col. 23, lines 10-13); said at least one pump 292 defining a single synchronous mechanical device such that said at least one pump 292, upon engaging with multiple ones 134,136 of said tubes, said fluids are synchronously pumped through said tubes by an action of said at least one pump 292 (Col. 23, lines 21-27); said tubes 134,136 being engageable in a single step operation by placing them between said at least one pump 292 and moving said at least one pump race 296 toward said at least one pump 292. (Col. 23, lines 8-13, 21-27)

With respect to **claim 14**: The at least one pump race 296 is connected to tubes 134,136, which are in turn connected to portions 22A/B/C which are in turn connected to tubing 80 having filter 82, thus the at least one pump race 296 is connected to a filter 82. (Col.19, lines 23-26, Col. 23, lines 10-13)

With respect to **claim 15**: The at least one pump race 296 is attached to said fluid circuit 18. (Col. 23, lines 14-20)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

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whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dennehey et al ('416) in view of Callan et al (U.S. Patent No. 6,610,206).

With respect to **claim 5**: Dennehey does not teach a replacement fluid. Callan teaches a dialysate precursor composition that maintains electrolytic balance and Callan teaches that the composition of the dialysate, or replacement fluid, and its use are well known in the art and the treated water component having the buffering anion which maintains electrolytic balance is standard in dialysis clinics (Col. 8, lines 43-57, Col. 9, lines 18-21), thus it would be obvious to one of ordinary skill in the art to modify the device of Dennehey to contain a drip chamber of dialysate such as that taught by Callan to maintain electrolytic balance in the bodily fluids of the patient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

January 19, 2007

**TATYANA ZALUKAEVA**  
**PRIMARY EXAMINER**

